K042576

DEC - 2 2004

Section 3
Coatest SP FVIII - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

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Carol Marble, Regulatory Affairs Director
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Summary Prepared:

September 21, 2004

Name of the Device:

Coatest SP FVIII

Classification Name:

864.7290	Factor Deficiency Test	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficiency	

Identification of predicate device:

K833892	Coatest Factor VIII

Description of the device:

Coatest SP FVIII is intended for the photometric determination of factor VIII activity in citrated plasma, such as when identifying factor VIII deficiency or monitoring patients on replacement therapy, as well as for potency estimation of FVIII concentrates.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

Coatest SP FVIII is substantially equivalent in performance and safety and effectiveness to the predicate device: Coatest Factor VIII.

Section 3 (Cont.)
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Summary of Performance Data:

Method Comparison

In method comparison studies evaluating citrated plasma samples, the slopes and correlation coefficients (r) obtained for Coatest SP FVIII versus the following reference methods showed statistically similar performances:

	Reference Method	n	Slope	r
Manual Method	Coatest FVIII (K833892)	181	1.0851	0.9873
ACL 9000	Coamatic FVIII (K981038)	90	0.9987	0.9919

Precision

Within run and total precision was assessed over multiple runs (n=80) using both normal and abnormal samples:

	Control	Mean % Factor VIII	Within run CV%	Total CV%
Manual Method	High Abnormal Control	14.4	4.3	5.6
	Normal Control	83	3.4	5.3
ACL 9000	High Abnormal Control	17.3	5.7	6.3
	Normal Control	102	4.7	7.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

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Re: k042576
Trade/Device Name: Coatest SP FVIII
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GGP
Dated: November 9, 2004
Received: November 10, 2004

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K042576

Device Name: Coatest SP FVIII

Indications for Use:

Coatest SP FVIII is intended for the photometric determination of factor VIII activity in citrated plasma, such as when identifying factor VIII deficiency or monitoring patients on replacement therapy, as well as for potency estimation of FVIII concentrates.

For *in vitro* diagnostic use.

Prescription Use √ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042576